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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/483,672	01/14/00	XU	J 210121.42711

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HM22/1106

EXAMINER	
MORAN, M	
ART UNIT	**PAPER NUMBER**
1631	18

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application No.	Applicant(s)	
	09/483,672	XU ET AL.	
	Examiner	Art Unit	
	Morjorie Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-18 and 21-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *65* is/are allowed.

6)☒ Claim(s) *66-69,71 and 72* is/are rejected.

7)☒ Claim(s) *70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *13* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Electi n/R strictions

Applicant's election of Group I, claims 1-3 and 19-22 and of SEQ ID NO: 525 in Paper No. 12, filed 8/20/01, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-18 and 23-64 and all SEQ ID NO's other than SEQ ID NO: 525 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

New claims 65-72 recite subject matter encompassed by elected Group I and are therefore considered elected. Claims 4-18 and 21-72 are pending. An action on the merits of elected claims 21-22 and 65-72, as they read on SEQ ID NO: 525, follows.

Priority

The instant application is a CIP of several previous applications. The examiner has searched all of the parent applications for a sequence corresponding to SEQ ID NO: 525. For those applications where no sequence match was found by computer alignment, the examiner reviewed the specifications for reference to any sequence termed "SEQ ID NO:525". Priority to SEQ ID NO: 525 could be found only in application numbers 09/443,686, filed 11/18/99 and 09/439,313, filed 11/12/99, therefore priority for claims reciting SEQ ID NO: 525 is granted only to 11/12/99. It is noted that mere reference to clone P703P, from which SEQ ID NO: 525 is isolated, is not sufficient to provide support for SEQ ID NO: 525 as several sequences have been isolated from the same clone.

Drawings

The drawings are objected to by the Draftsperson as set forth on Form PTO948. The following is a reminder of the rules regarding drawing changes:

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set forth for response to this Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Information Disclosure Statement

Not all references cited on Form 1449 (IDS), filed 10/30/01 as paper #8, have been considered for the following reasons: The IDS states that all references cited therein were submitted to and/or cited by the USPTO in parent applications. However, all of the references cited in the instant IDS were not found in parent applications. The examiner requested that copies of references not found in parent applications be supplied by applicant (see the Interview Summary of 10/25/01). No copies of the missing references were received by the examiner as

of the date of this Office Action. The Examiner obtained copies of some of the missing references from USPTO sources (e.g. STIC, on-line publications), but not all. References BL and BM, cited on page 2, and reference DJ, on page 4, recite accession numbers from Genbank or a "Derwent Geneseq Database". However, none of these accession numbers could be found in either the National Center for Biotechnology Information (NCBI) database nor in a Derwent sequence database (DGENE). The accession numbers cited in the IDS do not appear to be valid Genbank or Derwent accession numbers. As these references were not found by the examiner, were not supplied by applicant, and do not appear to cite valid accession numbers, they were not considered. References BL, BM, and DJ have been crossed out on the IDS to indicate non-consideration. All other references have been initialed to indicate that they have been considered.

Specification

The disclosure is objected to because of the following informalities: the US Patent application recited on page 1 as having been filed 11/18/99 is not identified by its application number. Appropriate correction is required.

Applicant is also requested to update the status of US patent applications disclosed in the specification (e.g. by inserting --, Patent number...., --), where appropriate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 21, 66, 69, and 71-72 are rejected under 35 U.S.C. 102(b) as being anticipated by BANDMAN et al. (US 5,786,148).

BANDMAN teaches an HPSK protein corresponding to her SEQ ID NO: 1 (col. 33-34), which is 88.8% identical to instant SEQ ID NO: 525.

Claim 66 appears to recite a "product-by-process". As set forth in MPEP 2113: ' "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).' As the peptide taught by BANDMAN is the same as the product recited in claim 66, BANDMAN anticipates claim 66. BANDMAN teaches that her protein may be used to produce antibodies (col. 16, lines 25-28), therefore claim 69 is anticipated. BANDMAN further teaches that her protein may be combined with adjuvants (col. 16, lines 40-52) or physiologically acceptable carriers (col. 19, lines 18-29), thereby anticipating claims 21 and 71-72.

Claims 21, 66-69 and 71-72 rejected under 35 U.S.C. 102(e) as being anticipated by GIMENO et al. (US 5,955,306).

GIMENO teaches a protein represented by his SEQ ID NO: 31 (col's 73-76), which is 97.6% identical to instant SEQ ID NO: 525, thereby anticipating claims 66-68.

See above regarding "product-by-process" claims. GIMENO teaches that his proteins are immunogenic (col. 29, lines 33-44) and may be mixed with an adjuvant for administration (col. 29, lines 47-48), thereby anticipating claims 21, 69 and 72. GIMENO also teaches that his proteins may be formulated in compositions with physiologically acceptable carriers (col. 33, lines 49-56), thereby anticipating claim 71.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-22, 66, 69, and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANDMAN et al. (US 5,786,148) in view of HAUSER et al. (US 5,776,468).

Claims 21-22, 66-69 and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIMENO et al. (US 5,955,306) in view of HAUSER et al. (US 5,776,468).

Claims 66-69 recite an isolated polypeptide comprising a sequence with at least 70%, 90%, or 95% identity to SEQ ID NO: 525. Claim 69 recites an isolated polypeptide comprising an immunogenic portion of SEQ ID NO: 525. Claim 71 recites a composition comprising one of the peptides recited in claims 66-69 and a physiologically acceptable carrier. Claim 72 recites a composition comprising one of the peptides recited in claims 66-69 and an immunostimulant. Claim 21 limits the immunostimulant to an adjuvant. Claim 22 limits the immunostimulant to one which elicits a Type I response.

BANDMAN teaches a peptide which is 88.8% identical to SEQ ID NO: 525, is immunogenic and may be formulated in a composition with a physiologically acceptable carrier or adjuvant, as set forth above. BANDMAN does not teach an immunostimulant which induces a Type I response.

GIMENO teaches a peptide which is 97.6% identical to SEQ ID NO: 525, is immunogenic and may be formulated in a composition with an adjuvant or physiologically acceptable carrier, as set forth above. GIMENO does not teach an immunostimulant which induces a Type I response.

HAUSER teaches an improved adjuvant, small MPL, which preferentially induces IgG2a, and induces a Type I response (col. 18, lines 5-30 and col. 28, lines 1-10).

It would have been obvious to one skilled in the art at the time of invention to have used HAUSER's MPL as an adjuvant in the compositions of either BANDMAN or GIMENO where the motivation would have been to use an improved adjuvant, and to induce production of specific (desired) antibodies, such as IgG2a, as suggested by HAUSER's teachings that MPL is an improved adjuvant compared to other known adjuvants, and his teaching that MPL specifically induces IgG2a production.

Allowable Subj ct Matter

The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor fairly suggests an isolated polypeptide comprising SEQ ID NO: 525.

Double Patenting

Claim 70 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 65. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 65 recites an isolated polypeptide comprising SEQ ID NO: 525. Claim 70 recites an isolated polypeptide encoded by SEQ ID NO: 524. The specification teaches, on page 25, that SEQ ID NO: 525 is the peptide sequence encoded by SEQ ID NO: 524, therefore claim 70 is directed to the same polypeptide as claim 65, and is a substantial duplicate thereof.

Conclusion

Claims 21-22, 66-69 and 71-72 are rejected; claims 4-18 and 23-64 are withdrawn. The specification and claim 70 are objected to. Claim 65 appears to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Marjorie A. Moran
November 2, 2001
Patent Examiner